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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,753	11/01/2000	Robert E. Dudley	9774100-0024	2099

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/05/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/703,753

Applicant(s)

DUDLEY, ROBERT E

Examiner

Shaojia A. Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002 and 22 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,35,36,41,42,45,48,49,57-59,62,64,75-83,88-93,97-99 and 101-210 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13, 16</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 33,35,36,41,42,45,48,49,57-59,62,64,75-83,88-93,97-99 and 101-210.

DETAILED ACTION

This Office Action is a response to Applicant's Request for Continued Examination (RCE) filed April 8, 2002 in Paper No. 15, and amendment and response to the Final Office Action (mailed November 23, 2001), filed February 22, 2002 in Paper No. 12 wherein claims 1-32, 37-40, 43, 44, 46-47, 51-56, 60-61, 63, 65-74, 84-87, 94-96, and 100 are cancelled and claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, and 97-99 have been amended; claims 102-210 are newly submitted. Currently, claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are pending in this application.

It is noted that claim 64 is dependent from claim 63 which is cancelled by the same amendment filed February 22, 2002.

Information Disclosure Statement (IDS)

It is noted that Applicants' IDS submitted March 28, 2002 in Paper No. 13 and Applicants' IDS submitted April 11, 2002 in Paper No. 16 are identical. Some non-patent literature documents, e.g., downloading from internet, have been crossed out as they are not appropriate for IDS, i.e., no name of author and no publication data (e.g., date and page) provided.

Applicant's amendment (canceling claims 84-87, 94, and 100) filed February 22, 2002 in Paper No. 12 with respect to the objection of claims 84-87, 94, and 100 made under 37 CFR 1.75 (c) for improper dependent for failing to further limit claims of record

stated in the Final Office Action dated November 23, 2001 have been fully considered and are found persuasive since claims 84-87, 94, and 100 have been cancelled.

Applicant's amendment (amending 35 and 41-43) filed February 22, 2002 in Paper No. 12 with respect to the rejection of claims 35 and 41-43 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions of record stated in the Office Action dated November 23, 2001 have been fully considered and found persuasive to remove the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 35-36, 41-42, 45, 48-49, 57-59, 62, 64, 75-83, 88-93, 97-99, and 101-210 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (WO 99/24041, of record in the Office Actions November 23, 2001 and April 24, 2001) and Heiber et al. (WO 93/25168, PTO-1449 submitted March 28, 2002 and April 11, 2002), and Omar (5,730,987, of record in the Office Actions November 23, 2001 and April 24, 2001) and Moreland et al. (of record in the Office Actions November 23, 2001 and April 24, 2001) in view of Allen (WO 96/227372, of record in the Office Actions November 23, 2001 and April 24, 2001).

Mak et al. discloses an enhancement of the penetration of transdermally (percutaneously) or topically applied a pharmaceutical composition comprising an active agent, testosterone, and a penetration-enhancing system that comprises oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and the gelling agent (a thickener), CARBOPOL (a polyacrylic acid). See abstract, page 3 lines 1-5, page 10 Example 1, and Figure 2.

Heiber et al. (WO 93/25168) discloses that testosterone compositions comprising a transdermal (percutaneous) delivery system comprising C2 or C3 alcohol, a penetration enhancer therein, i.e., glycerine, and a gelling agent, are useful in methods moderating and maintaining transdermal drug delivery to the derma at a relatively sustained rate over the duration of application to situs. See abstract, Example 3 at page 19-21, and claims 1-46 and 48.

Omar discloses that the particular steroid, testosterone and yohimbine HCl (ACTIBINE) or a combination thereof to be administered are useful in the composition and the method of the treatment of impotent in human males, i.e., erectile dysfunction. See col.1 lines 17-62 and claims 6-8.

Moreland et al. teaches that the phosphodiesterase type 5 inhibitor, sildenafil, is useful in the treatment of male erectile dysfunction. See Abstract and Introduction.

The prior art does not expressly disclose a method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male who may be an eugonadal comprising the particular steroid, testosterone, C1-C4 alcohol, and the

particular penetration enhancer, isopropyl myristate, and the effective amounts of active ingredients in the composition.

Allen discloses a topical cream composition useful for treating male erectile dysfunction comprising the particular penetration enhancer, isopropyl myristate or glycerine. See abstract and claim 1 and 4.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in a method for improving the efficacy of the composition herein useful for treating erectile dysfunction in a male who may be an eugonadal, and to further add the phosphodiesterase type 5 inhibitor, sildenafil or yohimbine HCl to the composition, and optimize the effective amounts of active ingredients in the composition.

One having ordinary skill in the art would have been motivated to employ the particular steroid, testosterone, C1-C4 alcohol, and the particular penetration enhancer, C8-C22 fatty acid and isopropyl myristate in a method for improving the efficacy of the composition herein useful for treating erectile dysfunction in an eugonadal male since the composition containing testosterone of Mak et al. is known to be useful in a method for improving the efficacy of percutaneously delivering a pharmaceutical because this composition further comprises a transdermally or topically penetration-enhancing system encompassing an oleic acid (a fatty acid having 17 carbon atoms), C1-C4 alcohol (e.g., ethanol, 2-propanol), and a penetration enhancer and a gelling agent. Moreover, the teachings of Heiber et al. have further provided the motivation to make

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the present invention since testosterone compositions of Heiber are known to comprise a transdermal (percutaneous) delivery system comprising C2 or C3 alcohol, a penetration enhancer therein, i.e., glycerine, and a gelling agent, and these compositions are known to be useful in methods moderating and maintaining transdermal drug delivery to the derma at a relatively sustained rate over the duration of application to situs.

The particular steroid, testosterone, is well known to be useful to treat erectile dysfunction in a male according to Omar. It is also well known that an eugonadal male suffers erectile dysfunction. Therefore, one of ordinary skill in the art would have found it obvious to employ the composition of Mak et al. in the instant claimed method. The topical cream composition of Allen is also known to be useful for treating male erectile dysfunction comprising the particular penetration enhancer herein, isopropyl myristate, which provides additional motivation for the claimed method.

One of ordinary skill in the art would also have been motivated to add the phosphodiesterase type 5 inhibitor, sildenafil or yohimbine HCl to the composition since the combination of testosterone and yohimbine HCl or yohimbine HCl alone or sildenafil are all known to be useful in the treatment of male erectile dysfunction according to Omar and Moreland. Therefore, one of ordinary skill in the art would have reasonably expected that adding yohimbine HCl or sildenafil to Mak's composition would improve the therapeutic effect of Mak's composition to treat male erectile dysfunction.

Additionally, one of ordinary skill in the art would have been motivated to optimize the

effective amounts of active ingredients in the composition because the optimization of amounts of active agents to be administered is considered well within the skill of artisan.

Since all composition components herein are known to be useful to treat male erectile dysfunction, it is considered *prima facie* obvious to combine them into a single composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

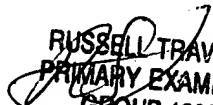
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. A. Jiang, Ph.D.
Patent Examiner, AU 1617
May 31, 2002


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